

Sub B' } -- 31. A pharmaceutical preparation for treating blood coagulation disorders, said preparation comprising an effective amount of vWF propeptide.

32. A preparation as set forth in claim 31, said preparation being essentially comprised of vWF propeptide.

33. A preparation as set forth in claim 31, comprising pro-vWF, said pro-vWF containing said vWF propeptide.

34. A preparation as set forth in claim 33, wherein said pro-vWF is a recombinant pro-vWF.

35. A preparation as set forth in claim 31, further comprising a hemostasis protein.

36. A preparation as set forth in claim 35, wherein said hemostasis protein is a blood factor.

37. A preparation as set forth in claim 36, wherein said blood factor is selected from the group consisting of mature vWF, factor VIII, activated blood coagulation factors, blood factors with FEIB activity and FEIBA.

38. A preparation as set forth in claim 33, further comprising factor VIII, said pro-vWF being complexed to said factor VIII.

39. A preparation as set forth in claim 31, further comprising a platelet component.

40. A preparation as set forth in claim 39, wherein said platelet component is at least one component selected from the group consisting of collagen, a platelet glycoprotein, a platelet, fibrinogen, fibrin, heparin and a derivative thereof.

Sub C.12 } 41. A preparation as set forth in claim 31, further comprising phospholipids.

42. A preparation as set forth in claim 31, said preparation having been treated for at least one of virus inactivation and virus removal.

43. A preparation as set forth in claim 31, further comprising a pharmaceutically acceptable carrier.

44. A preparation as set forth in claim 31, wherein said vWF propeptide is a recombinant vWF propeptide.

45. A method for producing a pharmaceutical preparation containing an effective amount of vWF propeptide, said method comprising providing a source material containing said vWF propeptide, separating said vWF propeptide from said source material, and formulating said vWF propeptide to a pharmaceutical preparation.

46. A method as set forth in claim 45, further comprising subjecting said vWF propeptide to at least one of a virus inactivation and a virus removing treatment.

47. A method as set forth in claim 45, wherein said source material is selected from the group consisting of plasma and a plasma fraction.

48. A method as set forth in claim 45, wherein said source material is obtained from a cell culture.

49. A method as set forth in claim 45, wherein said vWF propeptide is produced by recombinant DNA technology.

50. A method as set forth in claim 45, wherein said vWF propeptide is contained in a pro-vWF.

51. A method as set forth in claim 50, wherein said pro-vWF is a mutant pro-vWF with a mutation at the cleavage site of the vWF propeptide.

52. A method as set forth in claim 50, further comprising providing an inhibitor inhibiting cleavage of said vWF propeptide from said pro-vWF, said pharmaceutical preparation being produced in the presence of said inhibitor.

53. A method as set forth in claim 45, wherein said vWF propeptide is separated from said source material by chromatography.

54. A method as set forth in claim 53, wherein said chromatography is an affinity chromatography.

55. A method as set forth in claim 54, further comprising using carrier materials with ligands specific for said vWF propeptide for said affinity chromatography.

56. A method for treating a patient running a risk of a blood coagulation disorder comprising administering an effective dose of a pharmaceutical composition comprising at least one of a vWF propeptide and pro-vWF containing said vWF propeptide to said patient.

57. A method for treating and preventing blood coagulation disorders in a patient, comprising administering to said patient an effective dose of a pharmaceutical composition comprising at least one of a vWF propeptide and a pro-vWF containing said vWF propeptide.

58. A method as set forth in claim 57, wherein said patient is a vWD inhibitor patient.

59. A method of improving the compatibility of pharmaceutical vWF preparations, wherein at least one agent selected from the group consisting of pp-vWF and pro-vWF is administered to a patient when a pharmaceutical vWF preparation is administered to said patient.

60. A method for treating or preventing adverse effects of endogenous or exogenous vWF, wherein a pharmaceutical composition containing one of pp-vWF and pro-vWF is administered to a patient in an effective dose.

61. A method as set forth in claim 60, wherein said adverse effects are selected from the group consisting of elevated vWF levels associated with thrombotic thrombocytopenic purpura, Henoch-Schönlein Purpura, preclampsia, neonatal thrombocytopenia, hemolyticuremic syndrome, myocardial infarction and a poor outcome following arterial surgery.

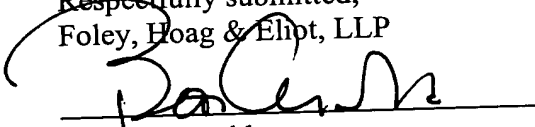
62. A method as set forth in claim 57, wherein said patient suffers from hemophilia.

63. A method as set forth in claim 52, wherein said hemophilia is selected from the group consisting of phenotypic hemophilia, hemophilia A and factor VIII inhibitors. - -

Applicants submit that the claims being added in the preliminary amendment and the specification are in compliance with all patentability requirements. Applicants therefore respectfully request that the claims be allowed. To expedite allowance, the Examiner is encouraged to contact Applicants' attorney at the number provided below.

Date: 11/24/99
Patent Group
One Post Office Square
Boston, Massachusetts 02109
Telephone: (617) 832-1177
Facsimile: (617) 832-7000

Respectfully submitted,
Foley, Hoag & Eliot, LLP


Beth E. Arnold
Registration No. 35,430
Attorney for Applicant